

(U.S. Patent No. 5,244,886, "Scholz *et al.*"). For the reasons set forth herein, each of these rejections is overcome.

2. **The Rejections Under 35 U.S.C. § 103**

a. Relevant Caselaw

In making an obviousness rejection based on close similarity in chemical structures, it has been held that the prior art should share the same utility as the claimed compounds. The premise underlying the motivation to modify structurally similar compounds derives from the expectation of one of skill in the art that such compounds will have similar properties. Where the prior art does *not* teach the utility asserted for the claimed compound, the claimed expectation may not arise, and the motivation would dissipate. For instance, in *In re Lulu*, 223 U.S.P.Q. 1257, 1259 (Fed. Cir. 1984), the Federal Circuit found that there was *no* motivation in the prior art reference to modify a reaction intermediate to obtain a structurally similar corrosion inhibiting compound. In reaching this conclusion, the Federal Circuit framed the obviousness analysis as requiring an inquiry into whether the prior art "would suggest an expected property of the claimed compounds" or whether the prior art discloses any utility of its compounds that "would support an expectation that the claimed compounds would have similar properties." More particularly, the Federal Circuit stated:

Ultimately our analysis of the obviousness or nonobviousness of appellants' claimed compounds requires inquiry as to whether there is anything in the Oesterling reference which would suggest the expected properties of the claimed compounds or whether Oesterling discloses any utility for the intermediate sulfonyl chlorides which would support an expectation that the claimed compounds would have similar properties.

Again, the Federal Circuit found no motivation in the prior art that would suggest the expected properties of the claimed compounds. (*See, also, In re Stemniski*, 170 USPQ 343, 347 (CCPA), wherein the prior art discloses no utility for disclosed compounds, no

motivation will be inferred to make the structural changes needed to arrive at the claimed compounds.)

Moreover, it has been found that when the prior art teaches *different* utilities for structurally similar compounds, the claimed compounds are nonobvious over the prior art teaching (*see, Ex parte Blattner*, 2 USPQ2d 2047, 2048 (Bd. Pat. App. & Int. 1987)). In *Ex parte Blattner*, the invention related to azatetracyclic compounds (a seven-membered ring compound) useful in the treatment of states of agitation in mammals. The Examiner rejected the claims as *prima facie* obvious in view of a prior art reference disclosing pyrrolidino and piperidino compounds, structurally similar to the claimed compounds except that they contained five- and six-membered rings, respectively.

In overturning the Examiner's obviousness rejection, the Board noted that the prior art disclosed that the pyrrolidino and piperidino compounds possessed diametrically opposite utilities. More particularly, the prior art disclosed that the pyrrolidino compounds were useful in treating stress and agitation, whereas piperidino compounds treated depression. The Board found that this difference in properties undermined the Examiner's asserted *prima facie* case of obviousness, premised on the expectation that compounds similar in structure will have similar properties. In holding that the prior art did not render the claimed compounds *prima facie* obvious, the Board indicated that the skilled person, given only the prior art reference without benefit of appellant's disclosure, "would not have had sufficient basis to predict what, if any, utility applicants' azepine compounds might possess" (*see, Id.* at 2048). In finding the claimed compounds nonobvious over the prior art teaching, the Board stated:

In conclusion the examiner's *prima facie* case of obviousness is based on the expectation that compounds which are similar in structure will have similar properties. ***The very prior art reference here relied on by the examiner, however, undermines the prima facie case because the reference teaches that compounds similar in structure in this art do not possess similar properties.***

Id. at 2048 (emphasis added).

b. Rejection Under 35 U.S.C. § 103(a) Over Torelli et al.

Claims 1, 2, 4-7, 15-19, 26 and 27 have been rejected under 35 U.S.C. § 103 as allegedly being obvious over Torelli *et al.* In maintaining this rejection, the Office Action alleges that although the instant invention differs from the Torelli, *et al.* reference by reciting compounds not exemplified by this reference, Torelli, *et al.* teach an equivalence between various substitutents (*see*, pages 2-3 of the Office Action mailed November 5, 2001). Applicants respectfully *disagree*.

i. Torelli et al. Do Not Teach the Compounds of Claim 1

A perusal of Torelli *et al.* reveals that they do *not* teach or suggest the compounds recited in amended claim 1. As noted in the Office Action, the instant invention differs from the Torelli *et al.* reference by reciting compounds not exemplified by the Torelli *et al.* reference (*see*, page 2 of the Office Action mailed November 5, 2001). The only compound disclosed by Torelli, *et al.* that arguably fell within the scope of the claim 1, as originally filed, is compound 10, which is recited at columns 15 and 16 of the Torelli *et. al* patent. This is true despite the fact that Torelli, *et al.* disclose pages upon pages of compounds. As previously explained, compound 10 is used in the present invention as an intermediate to form the other compounds of interest. Moreover, it is again pointed out that compound 10 has been explicitly excluded from amended claim 1. The remaining Torelli *et al.* compounds are structurally different from the compounds recited in amended claim 1.

ii. The Torelli et al. Compounds Possess Different Properties and, thus, Different Utilities Than the Compounds of Claim 1

In addition to being structurally different from the claimed compounds, the Torelli *et al.* compounds possess different properties and utilities from the claimed compounds. More particularly, as explained in the specification, one of the advantages of the compounds of the present invention (*i.e.*, the compounds of Formula I) is that they possess potent antiprogestational activity with minimal antiglucocorticoid activity (*see*,

the specification at, for example, page 1, lines 2-5; page 2, lines 19-20; and page 20, lines 20-21). In contrast to the compounds of the present invention, Torelli *et al.* explicitly state that the compounds disclosed therein have “remarkable antiglucocorticoid properties” (*see, e.g.*, column 38, lines 55-57 of Torelli, *et al.*).

As such, there is no teaching in the Torelli *et al.* reference which would suggest to one of skill in the art that the claimed compounds would possess potent antiprogestational properties with minimal antiglucocorticoid properties. To the contrary, based on the teachings of the Torelli *et al.* reference, one of skill in the art would expect the claimed compounds to have “remarkable antiglucocorticoid properties,” not potent antiprogestational properties with minimal antiglucocorticoid properties.

As was the case in *Ex parte Blattner, supra*, Torelli *et al.* teaches that the compounds disclosed therein possess fundamentally different properties and utilities. As such, the claimed compounds are nonobvious and, thus, patentable over Torelli *et al.* Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over Torelli *et al.* be withdrawn.

c. Rejection Under 35 U.S.C. § 103(a) Over Peeters et al.

Claims 1, 2, 4-7, 15-19, 26 and 27 have also been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Peeters *et al.* (U.S. Patent No. 5,741,787). In maintaining this rejection, the Office Action alleges that Peeters *et al.* disclose a generic group of 11-substituted steroids. Although the Office Action acknowledges that the instant claims differ from the Peeters *et al.* reference by reciting specific compounds not exemplified by the prior art, it nonetheless alleges that the claims are obvious because the Peeters *et al.* reference teaches an equivalence between various substituents in the 17 α -position (*see*, page 3 of the Office Action). Applicants respectfully *disagree*.

i. Peeters et al. Do Not Teach the Compounds of Claim 1

Peeters *et al.* disclose and claim the use of compounds having seven different points of substitution (*i.e.*, R₁, R₂, R₃, R₄, R₅, R₆ and R₇), with *numerous*

substituents being available for each of the seven different points of substitution (*see*, *e.g.*, column 1, line 54 through column 2, line 43, and claim 2). Based on a very conservative estimation, *millions* upon *millions* of compounds are encompassed by the generic formula disclosed by Peeters *et al.* Such a generic teaching is not tantamount to a teaching of the compounds of claim 1.

More particularly, according to the Federal Circuit in *In re Baird*, 29 U.S.P.Q.2d 1550 (Fed. Cir. 1994), a generic formula does not by itself necessarily render a compound encompassed by that formula obvious. In *In re Baird*, the invention included a generic formula which encompassed more than 100 million different compounds. Although the compound at issue was part of this generic formula, the Federal Circuit found *no* suggestion in the reference to select the particular substituents to produce the compound at issue. The same is true in the present case. There is *no* teaching or suggestion in the Peeters *et al.* reference to select the particular substituents from the lists of many, many different substituents to produce the compounds recited in claim 1.

ii. The Peeters *et al.* Compounds Possess Different Properties and, thus, Different Utilities Than the Compounds of Claim 1

In addition to the above, the Peeters *et al.* compounds possess *different* properties and utilities from the claimed compounds. More particularly, as explained above and in the specification, one of the advantages of the compounds of the present invention (*i.e.*, the compounds of Formula I) is that they possess potent antiprogestational activity with minimal antiglucocorticoid activity (*see*, the specification at, for example, page 1, lines 7-20, page 2, lines 28-30, *etc.*). In contrast to the compounds of the present invention, Peeters *et al.* explicitly state that the compounds disclosed therein are “antiglucocorticoid steroids” (*see, e.g.*, column 1, lines 6-8 of Peeters *et al.*). In fact, the Peeters *et al.* invention relates to the discovery that antiglucocorticoid steroids possess

anxiolytic effects, which make such steroids useful in the treatment of anxiety disorders (*see*, column 1, lines 22-24).

As such, there is no teaching in the Peeters *et al.* reference which would suggest to one of skill in the art that the claimed compounds would possess potent antiprogestational properties with minimal antiglucocorticoid properties. To the contrary, based on the teachings of the Peeters *et al.* reference, one of skill in the art would expect the claimed compounds to have “antiglucocorticoid properties,” not potent antiprogestational properties with minimal antiglucocorticoid properties.

In the same way that two compounds with greatly differing structures, but similar properties are *not* obvious over one another, two compounds with similar structures, but greatly differing properties are similarly *not* obvious over one another (*see, also, In re Papesch*, 137 U.S.P.Q. 43 (CCPA 1963)). As such, the claimed compounds are nonobvious and, thus, patentable over Peeters *et al.* Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over Peeters *et al.* be withdrawn.

d. Rejection Under 35 U.S.C. § 103(a) Over Scholz et al.

Claims 1, 2, 4-7, 15-19, 26 and 27 have also been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Scholz *et al.* (U.S. Patent No. 5,244,886). In citing Scholz *et al.*, the Office Action alleges that Scholz *et al.* disclose a generic group of 11-substituted 4,9-dienes and their use as antigestagens. Although the Office Action acknowledges that the instant claims differ from the Scholz *et al.* reference by reciting specific compounds not exemplified by the prior art, it nonetheless alleges that the claims are obvious because the Scholz *et al.* reference teaches an equivalence between various substituents in the 17 α -position (*see*, page 3 of the Office Action). Applicants respectfully *disagree*.

**i. Scholz *et al.* Disclose Compounds that are Structurally
Different from the Compounds of Claim 1**

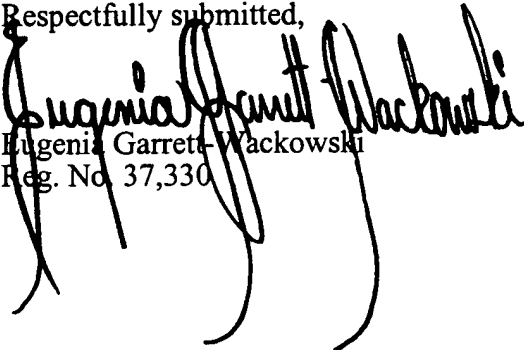
Scholz *et al.* do not teach or suggest compounds having the natural trans-anti configuration, *i.e.*, compounds of the present invention. Instead, Scholz *et al.* discloses compounds having the unnatural syn-anti configuration. To those of skill in the art (*e.g.*, steroid chemists), the disclosure of compounds having the unnatural syn-anti configuration does not teach or suggest compounds having the natural trans-anti configuration, *i.e.*, compounds of the present invention. More particularly, to one of skill in the art, compounds having the unnatural syn-anti configuration are structurally ***different*** from compounds having the natural trans-anti configuration. A perusal of the Scholz *et al.* reference reveals that there is no teaching or suggestion in this reference that would lead one of skill in the art to modify the compounds disclosed therein, *i.e.*, to modify the compounds having the unnatural syn-anti configuration so that they have the natural trans-anti configuration. Absent such a teaching or suggestion, the claimed compounds are non-obvious and, thus, patentable. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) over Scholz *et al.* be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,


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